Post market surveillance risk assesment re-evaluation

Oxygen Tents/Hoods Nova

Enclosures to enable oxygen enriched air and humidity to be supplied to the patients head only.

Class IIa
Via Rule Rule 2
Assesment Route Annex II
NBOG MD 0101

Carried out by Derek Lamb
02 / 10 / 17

VIAMED

- Stock References Review
- Supplier Review
- Sales Review
- Countries Review
- Returns Review
- Design Changes Review
- User Instructions Review
- Labels Review
- Document Updates Review
- Internal Issues Review
- Clinical / FDA Incidents online search
- Risk ISO 14971 : 2012 Review

Stock References Review

Stock Reference	Description
2310000	Oxygen hood/tent - standard.
2310001	Oxygen hood/tent - standard.
2310002	Oxygen hood/tent - standard.
2310003	Oxygen hood/tent - standard.
2310004	Oxygen hood/tent - standard.
2310005	Oxygen hood/tent - standard.
2310006	Oxygen hood/tent - standard.
2310007	Oxygen hood/tent - standard.
2310008	Oxygen hood/tent - standard.
2310009	Oxygen hood/tent - standard.
2310010	Oxygen hood/tent - standard.
2310011	Oxygen hood/tent - standard.
2310012	Oxygen hood/tent - standard.
2310013	Oxygen hood/tent - standard.
2310014	Oxygen hood/tent - standard.
2310020	Oxygen hood/tent - dual port.
2310021	Oxygen hood/tent - ICN with 3 ports.
2310025	Oxygen hood/tent - no bottom.
2310026	Oxygen hood/tent - no bottom.
2310027	Oxygen hood/tent - no bottom.
2310028	Oxygen hood/tent - no bottom.
2310029	Oxygen hood/tent - no bottom.
2310030	Oxygen hood/tent - no bottom.
2310031	Oxygen hood/tent - no bottom.
2310032	Oxygen hood/tent - no bottom.
2310033	Oxygen hood/tent - no bottom.
2310034	Oxygen hood/tent - no bottom.
2310035	Oxygen hood/tent - no bottom.
2310050	Oxygen hood/tent - partial bottom.
2310051	Oxygen hood/tent - partial bottom.
2310052	Oxygen hood/tent - partial bottom.
2310053	Oxygen hood/tent - partial bottom.
2310054	Oxygen hood/tent - partial bottom.
2310055	Oxygen hood/tent - partial bottom.
2310075	Oxygen hood/tent - NICU.
2310076	Oxygen hood/tent - NICU.
2310077	Oxygen hood/tent - NICU.
2310078	Oxygen hood/tent - NICU.
2310079	Oxygen hood/tent - NICU.
2310080	Oxygen hood/tent - NICU.
2310081	Oxygen hood/tent - NICU.
2310100	Low birth weight tenthouse

Stock Reference	Description
2310101	Low birth weight tenthouse w/port
2310102	Low birth weight tenthouse top access
2310103	Low birth weight tenthouse with top &
2310104	Low birth weight tenthouse
2310105	Low birt weight tenthouse w/port.
2310106	Low birth weight tenthouse top access
2310107	Low birth weight tenthouse with top &
2310125	Double tent set
2310126	Double tent set
2310127	Double tent set
2310128	Double tent set inner no bottom
2310129	Double tent set
2310130	Double tent set
2310131	Double tent - outer tent only for use
2310132	Double tent - outer tent only for use
2310133	Double tent - outer tent only for use
2310134	Double tent - outer tent only for use
2310140	Babyshield - infant heat shield
2310141	Babyshield - infant heat shield with
2310145	Oxygen hood - no drape.
2310150	Isolation canopy - chair.
2310151	Isolation canopy - crib.
2330000	Oxygen hood/tent - standard.
2330001	Oxygen hood/tent - standard.
2330002	Oxygen hood/tent - standard.
2330003	Oxygen hood/tent - standard.
2330004	Oxygen hood/tent - standard.
2330006	Oxygen hood/tent - standard.
2330007	Oxygen hood/tent - standard.
2330010	Oxygen hood/tent - standard.
2330011	Oxygen hood/tent - standard.
2330013	Oxygen hood/tent - standard.
2330014	Oxygen hood/tent - standard.
2330020	Oxygen hood/tent - dual port.
2330021	Oxygen hood/tent - ICN with 3 ports.
2330025	Oxygen hood/tent - no bottom.
2330026	Oxygen hood/tent - no bottom.
2330027	Oxygen hood/tent - no bottom.
2330028	Oxygen hood/tent - no bottom.
2330029	Oxygen hood/tent - no bottom.
2330031	Oxygen hood/tent - no bottom.
2330032	Oxygen hood/tent - no bottom.
2330035	Oxygen hood/tent - no bottom.
2330050	Oxygen hood/tent - partial bottom.
2330052	Oxygen hood/tent - partial bottom.

Stock Reference	Description
2330053	Oxygen hood/tent - partial bottom.
2330055	Oxygen hood/tent - partial bottom.
2330075	Oxygen hood/tent - NICU.
2330076	Oxygen hood/tent - NICU.
2330077	Oxygen hood/tent - NICU.
2330078	Oxygen hood/tent - NICU.
2330080	Oxygen hood/tent - NICU.
2330081	Oxygen hood/tent - NICU.
2330100	Low birthweight tenthouse
2330101	Low birthweight tenthouse w/port
2330103	Low birthweight tenthouse with top &
2330104	Low birthweight tenthouse
2330105	Low birthweight tenthouse w/port.
2330107	Low birthweight tenthouse with top &
2330125	Double tent set
2330126	Double tent set
2330127	Double tent set
2330128	Double tent set inner no bottom
2330129	Double tent set
2330130	Double tent set
2330131	Double tent - outer tent only for use
2330132	Double tent - outer tent only for use
2330133	Double tent - outer tent only for use
2330134	Double tent - outer tent only for use
2330140	Babyshield - infant heat shield
2330141	Babyshield - infant heat shield with
2330500	Label for Oxygen hoods & plastics...
2330501	Label for Oxygen hoods & plastics...

Comments on Stock references review:

part numbers upto date

Supplier Review

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
2310000	Oxygen hood/tent - stand	00012241	903011	Peace Medical (Formaly N	B
2310001	Oxygen hood/tent - stand	00012241	903202	Peace Medical (Formaly N	B
2310002	Oxygen hood/tent - stand	00012241	900800	Peace Medical (Formaly N	B
2310003	Oxygen hood/tent - stand	00012241	903081	Peace Medical (Formaly N	B
2310004	Oxygen hood/tent - stand	00012241	903012	Peace Medical (Formaly N	B
2310006	Oxygen hood/tent - stand	00012241	903213	Peace Medical (Formaly N	B
2310007	Oxygen hood/tent - stand	00012241	903013	Peace Medical (Formaly N	B
2310010	Oxygen hood/tent - stand	00012241	903014	Peace Medical (Formaly N	B
2310011	Oxygen hood/tent - stand	00012241	907011	Peace Medical (Formaly N	B
2310013	Oxygen hood/tent - stand	00012241	903015	Peace Medical (Formaly N	B
2310014	Oxygen hood/tent - stand	00012241	907024	Peace Medical (Formaly N	B
2310020	Oxygen hood/tent - dual	00012241	903022	Peace Medical (Formaly N	B
2310021	Oxygen hood/tent - ICN w	00012241	903092	Peace Medical (Formaly N	B
2310025	Oxygen hood/tent - no bo	00012241	903101	Peace Medical (Formaly N	B
2310026	Oxygen hood/tent - no bo	00012241	903016	Peace Medical (Formaly N	B
2310027	Oxygen hood/tent - no bo	00012241	903201	Peace Medical (Formaly N	B
2310028	Oxygen hood/tent - no bo	00012241	903082	Peace Medical (Formaly N	B
2310029	Oxygen hood/tent - no bo	00012241	903017	Peace Medical (Formaly N	B
2310031	Oxygen hood/tent - no bo	00012241	903214	Peace Medical (Formaly N	B
2310032	Oxygen hood/tent - no bo	00012241	903018	Peace Medical (Formaly N	B
2310035	Oxygen hood/tent - no bo	00012241	903094	Peace Medical (Formaly N	B
2310050	Oxygen hood/tent - parti	00012241	903049	Peace Medical (Formaly N	B
2310052	Oxygen hood/tent - parti	00012241	903019	Peace Medical (Formaly N	B
2310055	Oxygen hood/tent - parti	00012241	903020	Peace Medical (Formaly N	B
2310075	Oxygen hood/tent - NICU.	00012241	903005	Peace Medical (Formaly N	B
2310076	Oxygen hood/tent - NICU.	00012241	903008	Peace Medical (Formaly N	B
2310077	Oxygen hood/tent - NICU.	00012241	903009	Peace Medical (Formaly N	B
2310078	Oxygen hood/tent - NICU.	00012241	903006	Peace Medical (Formaly N	B
2310080	Oxygen hood/tent - NICU.	00012241	903215	Peace Medical (Formaly N	B
2310081	Oxygen hood/tent - NICU.	00012241	903007	Peace Medical (Formaly N	B
2310100	Low birth weight tenthou	00012241	903200	Peace Medical (Formaly N	B
2310104	Low birth weight tenthou	00012241	903301	Peace Medical (Formaly N	B
2310107	Low birth weight tenthou	00012241	903307	Peace Medical (Formaly N	B
2310125	Double tent set	00012241	903028	Peace Medical (Formaly N	B
2310140	Babyshield - infant heat	00012241	909028	Peace Medical (Formaly N	B
2310141	Babyshield - infant heat	00012241	909030	Peace Medical (Formaly N	B

Comments on Suppliers:

new supplier, peace medical bought out nova,
not been able to gather a new agreement or confirmation of ISO status,

We are opting to drop the product range

Sales Information

Stock Reference	Description	2011	2012	2013	2014	2015	2016	2017
2310000	Oxygen hood/tent - stand	3	-3	1			4	
2310001	Oxygen hood/tent - stand		5	4	6	1	6	
2310002	Oxygen hood/tent - stand	6						
2310003	Oxygen hood/tent - stand		1	2	2	1	1	1
2310004	Oxygen hood/tent - stand		2	5	1	4	4	1
2310005	Oxygen hood/tent - standard.							
2310006	Oxygen hood/tent - stand	22	2	9	4			
2310007	Oxygen hood/tent - stand	49	25	34	18	29	13	
2310008	Oxygen hood/tent - standard.							
2310009	Oxygen hood/tent - standard.							
2310010	Oxygen hood/tent - stand	91	60	51	44	44	35	38
2310011	Oxygen hood/tent - stand							
2310012	Oxygen hood/tent - standard.							
2310013	Oxygen hood/tent - stand	43	28	30	18	23	14	3
2310014	Oxygen hood/tent - stand	10						
2310020	Oxygen hood/tent - dual							
2310021	Oxygen hood/tent - ICN w							
2310025	Oxygen hood/tent - no bo			1				
2310026	Oxygen hood/tent - no bo				1			
2310027	Oxygen hood/tent - no bo				2			
2310028	Oxygen hood/tent - no bo				2			
2310029	Oxygen hood/tent - no bo	28		2	6	0	15	
2310030	Oxygen hood/tent - no bottom.							
2310031	Oxygen hood/tent - no bo	5	4		2	1	12	
2310032	Oxygen hood/tent - no bo	42	21	14	31	8	5	3
2310033	Oxygen hood/tent - no bottom.							
2310034	Oxygen hood/tent - no bottom.							
2310035	Oxygen hood/tent - no bo	45	33	37	31	44	30	2
2310050	Oxygen hood/tent - parti							
2310051	Oxygen hood/tent - partial bottom.							
2310052	Oxygen hood/tent - parti		4	2	1	3		
2310053	Oxygen hood/tent - partial bottom.							
2310054	Oxygen hood/tent - partial bottom.							
2310055	Oxygen hood/tent - parti			2		3		
2310075	Oxygen hood/tent - NICU.							
2310076	Oxygen hood/tent - NICU.							
2310077	Oxygen hood/tent - NICU.							
2310078	Oxygen hood/tent - NICU.							
2310079	Oxygen hood/tent - NICU.							
2310080	Oxygen hood/tent - NICU.							
2310081	Oxygen hood/tent - NICU.							
2310100	Low birth weight tenthou							

Stock Reference	Description	2011	2012	2013	2014	2015	2016	2017
2310101	Low birth weight tenthouse w/port							
2310102	Low birth weight tenthouse top access							
2310103	Low birth weight tenthouse with top &							
2310104	Low birth weight tenthou							
2310105	Low birt weight tenthouse w/port.							
2310106	Low birth weight tenthouse top access							
2310107	Low birth weight tenthou							
2310125	Double tent set							
2310126	Double tent set							
2310127	Double tent set							
2310128	Double tent set inner no bottom							
2310129	Double tent set							
2310130	Double tent set							
2310131	Double tent - outer tent only for use							
2310132	Double tent - outer tent only for use							
2310133	Double tent - outer tent only for use							
2310134	Double tent - outer tent only for use							
2310140	Babyshield - infant heat							
2310141	Babyshield - infant heat							
2310145	Oxygen hood - no drape.							
2310150	Isolation canopy - chair.							
2310151	Isolation canopy - crib.							
2330000	Oxygen hood/tent - standard.	1						
2330001	Oxygen hood/tent - standard.	1			1			
2330002	Oxygen hood/tent - standard.	4						
2330003	Oxygen hood/tent - standard.							
2330004	Oxygen hood/tent - standard.				1			
2330006	Oxygen hood/tent - standard.							
2330007	Oxygen hood/tent - standard.							
2330010	Oxygen hood/tent - standard.				1			
2330011	Oxygen hood/tent - standard.							
2330013	Oxygen hood/tent - standard.				2			
2330014	Oxygen hood/tent - standard.		1					
2330020	Oxygen hood/tent - dual port.							
2330021	Oxygen hood/tent - ICN with 3 ports.							
2330025	Oxygen hood/tent - no bottom.							
2330026	Oxygen hood/tent - no bottom.							
2330027	Oxygen hood/tent - no bottom.							
2330028	Oxygen hood/tent - no bottom.							
2330029	Oxygen hood/tent - no bottom.							
2330031	Oxygen hood/tent - no bottom.		1					
2330032	Oxygen hood/tent - no bottom.							
2330035	Oxygen hood/tent - no bottom.		4		1			
2330050	Oxygen hood/tent - partial bottom.							
2330052	Oxygen hood/tent - partial bottom.							

Stock Reference	Description	2011	2012	2013	2014	2015	2016	2017
2330053	Oxygen hood/tent - partial bottom.							
2330055	Oxygen hood/tent - partial bottom.							
2330075	Oxygen hood/tent - NICU.	1						
2330076	Oxygen hood/tent - NICU.							
2330077	Oxygen hood/tent - NICU.							
2330078	Oxygen hood/tent - NICU.							
2330080	Oxygen hood/tent - NICU.							
2330081	Oxygen hood/tent - NICU.							
2330100	Low birthweight tenthouse							
2330101	Low birthweight tenthouse w/port							
2330103	Low birthweight tenthouse with top &							
2330104	Low birthweight tenthouse							
2330105	Low birthweight tenthouse w/port.							
2330107	Low birthweight tenthouse with top &							
2330125	Double tent set							
2330126	Double tent set							
2330127	Double tent set							
2330128	Double tent set inner no bottom							
2330129	Double tent set							
2330130	Double tent set							
2330131	Double tent - outer tent only for use							
2330132	Double tent - outer tent only for use							
2330133	Double tent - outer tent only for use							
2330134	Double tent - outer tent only for use							
2330140	Babyshield - infant heat shield							
2330141	Babyshield - infant heat shield with							
2330500	Label for Oxygen hoods & plastics...							
2330501	Label for Oxygen hoods & plastics...							

Comments on Sales Information:

units selling but not in good numbers,
and due to difficulties gathering information from current supplier we are dropping the product range

Countries Review

Country	2011	2012	2013	2014	2015	2016	2017
B Belgium				[X]			
F France							
G Germany				[X]			
GR Greece			[X]				[X]
IRE Ireland	[X]	[X]	[X]	[X]		[X]	[X]
IS Israel						[X]	
IT Italy				[X]	[X]		
JO Jordan							
K South Korea					[X]		
NE Netherlands	[X]						
P Poland	[X]	[X]					
RO Romania					[X]		
SP Spain			[X]				
SW Sweden	[X]						
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]

Comments on Sales to Countries:

selling in limited counties,
no new countries

Comments on Risks with Sales to Countries:

no new countries

Returns and Q.A. Fails Review

Stock Reference	Fault	2011	2012	2013	2014	2015	2016	2017
2310000	Unchecked - Returned To Stock	3						

Comments on Returns:

no failures, just a return to stock

Comments on Risks with Returns and Potential Re-work:

no risks identified

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

no design changes,

Comments on Risks with Design Changes:

no risks found

User Instructions Review

Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
13626	Oxygen Hoods Instructions for Use User Manual Italian	07/04/14
9084	Nova Oxygen Tents Cleaning Instructions	18/10/11
8969	Nova Oxygen Tents Instructions for Use / User Manual	18/10/11

Comments on User Instructions:

no ifu changes

Comments on Risks User Instructions:

no risks identified

Labels Review

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
8977	Nova Oxygen Tents Packaging Trials and validation Handling infor...	18/10/11
8961	Nova Oxygen Tents Accessory Labels List of Accessories	18/10/11
7690	Nova Oxygen Tents Labels	15/02/11

Comments on Labels:

no changes to labels

Comments on Risks Labels:

no risks identified

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
17428	Viamed CE Certificate CE01389	07/09/16
17272	Nova Oxygen Tents Clinical Trials Reports Reviews and Post Marke...	15/08/16

Comments on Document Changes:

linked our CE certificate to file,
no other changes

Comments on Risks with Document Changes:

no changes

Internal Issues Review

Number of Issues reviewed: 62

Issue ID	Subject
80261	Office Meeting Sales Back Orders Review - By Customer Backorder 00000290 2310010 ORD82548
97884	Office Meeting Sales Back Orders Review - By Customer Backorder 00000290 2310013 ORD87076
77035	Office Meeting Sales Back Orders Review - By Customer Backorder 00000950 2310032 ORD81856
77792	Office Meeting Sales Back Orders Review - By Customer Backorder 00000950 2310035 ORD82003
84155	Office Meeting Sales Back Orders Review - By Customer Backorder 00000950 2310035 ORD83565
84224	Office Meeting Sales Back Orders Review - By Customer Backorder 00000950 2310035 ORD83574
84618	Office Meeting Sales Back Orders Review - By Customer Backorder 00000950 2310035 ORD83663
84964	Office Meeting Sales Back Orders Review - By Customer Backorder 00000950 2310035 ORD83792
84439	Office Meeting Sales Back Orders Review - By Customer Backorder 00001415 2310035 ORD83610
80622	Office Meeting Sales Back Orders Review - By Customer Backorder 00001902 2310010 ORD82630
80884	Office Meeting Sales Back Orders Review - By Customer Backorder 00001902 2310010 ORD82683
89653	Office Meeting Sales Back Orders Review - By Customer Backorder 00001902 2310010 ORD84994
92628	Office Meeting Sales Back Orders Review - By Customer Backorder 00001902 2310010 ORD85772
91063	Office Meeting Sales Back Orders Review - By Customer Backorder 00002960 2310035 ORD85362
91619	Office Meeting Sales Back Orders Review - By Customer Backorder 00002960 2310035 ORD85452
84711	Office Meeting Sales Back Orders Review - By Customer Backorder 00004113 2310001 ORD83706
84968	Office Meeting Sales Back Orders Review - By Customer Backorder 00004113 2310001 ORD83800
77749	Office Meeting Sales Back Orders Review - By Customer Backorder 00004200 2310013 ORD81987
85816	Office Meeting Sales Back Orders Review - By Customer Backorder 00004200 2310013 ORD84076
95558	Office Meeting Sales Back Orders Review - By Customer Backorder 00007148 2310010 ORD86529
86735	Office Meeting Sales Back Orders Review - By Customer Backorder 00007374 2310004 ORD84261
82564	Office Meeting Product Feedback Negative Disposable hoods - quality issues reported by 2 customers
82563	Office Meeting Product Feedback Negative Disposable hoods - quality issues reported by 2 customers
82562	Office Meeting Product Feedback Negative Disposable hoods - quality issues reported by 2 customers

Issue ID	Subject
76990	Office Meeting GHX Web Pricing Missing images in Export Data
61711	Office Meeting Stock Processing Oxygen Hoods to dispose of
81079	Office Meeting Back Order Report POR10950 2310004 //
81029	Office Meeting Back Order Report POR10950 2310004 //
79404	Office Meeting Back Order Report POR10950 2310004 //
81080	Office Meeting Back Order Report POR10950 2310007 //
81030	Office Meeting Back Order Report POR10950 2310007 //
79405	Office Meeting Back Order Report POR10950 2310007 //
81081	Office Meeting Back Order Report POR10950 2310010 //
81031	Office Meeting Back Order Report POR10950 2310010 //
79406	Office Meeting Back Order Report POR10950 2310010 //
81082	Office Meeting Back Order Report POR10950 2310035 //
81032	Office Meeting Back Order Report POR10950 2310035 //
79407	Office Meeting Back Order Report POR10950 2310035 //
81083	Office Meeting Back Order Report POR10951 2310010 //
81027	Office Meeting Back Order Report POR10951 2310010 //
79402	Office Meeting Back Order Report POR10951 2310010 //
81084	Office Meeting Back Order Report POR10951 2310013 //
81028	Office Meeting Back Order Report POR10951 2310013 //
79403	Office Meeting Back Order Report POR10951 2310013 //
81085	Office Meeting Back Order Report POR10952 2310013 //
81025	Office Meeting Back Order Report POR10952 2310013 //
79379	Office Meeting Back Order Report POR10952 2310013 //
81086	Office Meeting Back Order Report POR10952 2310035 //
81026	Office Meeting Back Order Report POR10952 2310035 //
79380	Office Meeting Back Order Report POR10952 2310035 //

Issue ID	Subject
86324	Office Meeting Back Order Report POR11083 2310000 //
85210	Office Meeting Back Order Report POR11083 2310000 //
86325	Office Meeting Back Order Report POR11083 2310001 //
85211	Office Meeting Back Order Report POR11083 2310001 //
86326	Office Meeting Back Order Report POR11083 2310004 //
85212	Office Meeting Back Order Report POR11083 2310004 //
86327	Office Meeting Back Order Report POR11083 2310010 //
85213	Office Meeting Back Order Report POR11083 2310010 //
86328	Office Meeting Back Order Report POR11083 2310035 //
85214	Office Meeting Back Order Report POR11083 2310035 //
97869	Office Meeting Back Order Report POR11330 2310010 //
97790	Office Meeting Back Order Report POR11330 2310010 //

Comments on Issues:

82562 VIAMED Feedback Product Feedback Negative Product Feedback Negative

we checked stock, did not find anything similar, we chased several time to get the items back, its been confirmed the hospital disposed of them.

in light of no other reports and our stock being ok we have closed the issue

Comments on Risks with Issues:

no risks

Clinical / FDA Incidents online search

Clinical Investigation online review

Do any of the Results indicate a Risk / Problem : No
Do any of the Results indicate outdated Technology : No
Comments on Clinical Search :

no clinical reports found

Review of online FDA Incident reports

Do any of the Results indicate a Risk / Problem :
Do any of the Results indicate outdated Technology :
Comments on Clinical Search :

no fda reports found

Risk ISO 14971 : 2012 Summary

02 Oct 2017 File 8 Oxygen Tents/Hoods Nova Risk Assesment Questions

Risk Action

	Negligible	Minor	Serious	Critical	Catastrophic
Improbable	No Action	No Action	No Action	Risk Benefits	Unacceptable
Remote	No Action	No Action	Risk Benefits	Unacceptable	Unacceptable
Occasinal	No Action	Risk Benefits	Unacceptable	Unacceptable	Unacceptable
Probable	Risk Benefits	Unacceptable	Unacceptable	Unacceptable	Unacceptable
Frequent	Unacceptable	Unacceptable	Unacceptable	Unacceptable	Unacceptable

C.2.1 What is the intended use and how is the medical device to be used

ID	Ref Question	Applys	Risk	Probability	Overall
[1]	what is the medical device`s role relative to diagnosis,	No	---	---	n/a
[2]	what is the medical device`s role relative to prevention	No	---	---	n/a
[3]	what is the medical devices role relative to monitoring	No	---	---	n/a
[4]	what is the medical devices role relative to treatment	Yes	Minor	Occasinal	Risk Benefits
[5]	what is the medical devices role relative to alleviation of disease	No	---	---	n/a
[6]	what is the medical devices role relative to compensation for injury or handicap	No	---	---	n/a
[7]	what is the medical devices role relative to replacement or modification of anatomy	No	---	---	n/a
[8]	what is the medical devices role relative to control of conception	No	---	---	n/a
[9]	does the medical device sustain life	No	---	---	n/a
[10]	does the medical device support life	No	---	---	n/a
[11]	is special intervention necessary in the case of failure of the medical device	No	---	---	n/a
[330]	What are the indications for use e.g. patient population	No	---	---	n/a

C.2.10 Is the medical device intended to modify the patient environment

ID	Ref Question	Applys	Risk	Probability	Overall
[56]	Factors that should be considered include temperature	Yes	Minor	Remote	No Action
[57]	Factors that should be considered include humidity	Yes	Minor	Improbable	No Action
[58]	Factors that should be considered include atmospheric gas composition NOTES: CO2 build up	Yes	Minor	Remote	No Action
[59]	Factors that should be considered include pressure	No	---	---	n/a
[60]	Factors that should be considered include light	No	---	---	n/a

C.2.11 Are measurements taken

ID	Ref Question	Applys	Risk	Probability	Overall
[61]	Factors that should be considered include the variables measured and the accuracy and the precision of the measurement results.	No	---	---	n/a

C.2.12 Is the medical device interpretative

ID	Ref Question	Applys	Risk	Probability	Overall
[62]	Factors that should be considered include whether conclusions are presented by the medical device from input or acquired data	No	---	---	n/a
[63]	Factors that should be considered include whether conclusions are presented by the medical device from the algorithms used	No	---	---	n/a
[64]	Factors that should be considered include whether conclusions are presented by the medical device from the confidence limits	No	---	---	n/a
[65]	Factors that should be considered include whether conclusions are presented by the medical device. Special attention should be given to unintended applications of the data or algorithm	No	---	---	n/a

C.2.13 Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies

ID	Ref Question	Applys	Risk	Probability	Overall
[66]	Factors that should be considered include identifying any other medical devices	Yes	Minor	Remote	No Action
[67]	Factors that should be considered include identifying any other medicines	No	---	---	n/a
[68]	Factors that should be considered include identifying any other medical technologies that can be involved	No	---	---	n/a

C.2.14 Are there unwanted outputs of energy or substances

ID	Ref Question	Applys	Risk	Probability	Overall
[69]	Energy-related factors that should be considered include vibration,	No	---	---	n/a
[70]	Energy-related factors that should be considered include heat,	No	---	---	n/a
[71]	Energy-related factors that should be considered include radiation,	No	---	---	n/a
[72]	Energy-related factors that should be considered include noise,	No	---	---	n/a
[73]	Energy-related factors that should be considered include ionizing radiation,	No	---	---	n/a
[74]	Energy-related factors that should be considered include non-ionizing radiation,	No	---	---	n/a

ID	Ref Question	Applys	Risk	Probability	Overall
[75]	Energy-related factors that should be considered include ultraviolet/ radiation,	No	---	---	n/a
[76]	Energy-related factors that should be considered include visible radiation,	No	---	---	n/a
[77]	Energy-related factors that should be considered include infrared radiation,	No	---	---	n/a
[78]	Energy-related factors that should be considered include contact temperatures	No	---	---	n/a
[79]	Energy-related factors that should be considered include leakage currents	No	---	---	n/a
[80]	Energy-related factors that should be considered include electric fields	No	---	---	n/a
[81]	Energy-related factors that should be considered include magnetic fields	No	---	---	n/a
[82]	Substance-related factors that should be considered include substances used in manufacturing	No	---	---	n/a
[83]	Substance-related factors that should be considered include substances used in cleaning	No	---	---	n/a
[84]	Substance-related factors that should be considered include substances used in testing	No	---	---	n/a
[85]	Other substance-related factors that should be considered include discharge of chemicals	No	---	---	n/a
[86]	Other substance-related factors that should be considered include waste products	No	---	---	n/a
[87]	Other substance-related factors that should be considered include body fluids	No	---	---	n/a

C.2.15 Is the medical device susceptible to environmental influences

ID	Ref Question	Applys	Risk	Probability	Overall
[88]	Factors that should be considered include the operational environment	No	---	---	n/a
[89]	Factors that should be considered include the transport environment	No	---	---	n/a
[90]	Factors that should be considered include the storage environment	No	---	---	n/a
[91]	Factors that should be considered include light	No	---	---	n/a
[92]	Factors that should be considered include temperature	No	---	---	n/a
[93]	Factors that should be considered include humidity	No	---	---	n/a
[94]	Factors that should be considered include vibrations	No	---	---	n/a
[95]	Factors that should be considered include spillage	No	---	---	n/a
[96]	Factors that should be considered include susceptibility to variations in power	No	---	---	n/a
[97]	Factors that should be considered include susceptibility to variations in cooling supplies	No	---	---	n/a
[98]	Factors that should be considered include susceptibility to variations in electromagnetic interference	No	---	---	n/a

C.2.16 Does the medical device influence the environment

ID	Ref Question	Applys	Risk	Probability	Overall
[99]	Factors that should be considered include the effects on power and cooling supplies	No	---	---	n/a
[100]	Factors that should be considered include the emission of toxic materials	No	---	---	n/a
[101]	Factors that should be considered include the generation of electromagnetic disturbance	No	---	---	n/a

C.2.17 Are there essential consumables or accessories associated with the medical device

ID	Ref Question	Applys	Risk	Probability	Overall
[102]	Factors that should be considered include specifications for such consumables	No	---	---	n/a
[103]	Factors that should be considered include specifications for such accessories	No	---	---	n/a
[104]	Factors that should be considered include any restrictions placed upon users in their selection of consumables.	No	---	---	n/a
[105]	Factors that should be considered include any restrictions placed upon users in their selection of accessories.	No	---	---	n/a

C.2.18 Is maintenance or calibration necessary

ID	Ref Question	Applys	Risk	Probability	Overall
[106]	Factors that should be considered include whether maintenance or calibration are to be carried out by the operator	No	---	---	n/a
[107]	Factors that should be considered include whether maintenance or calibration are to be carried out by the user	No	---	---	n/a
[108]	Factors that should be considered include whether maintenance or calibration are to be carried out by the specialist	No	---	---	n/a
[109]	Factors that should be considered include are special substances or equipment necessary for proper maintenance	No	---	---	n/a
[110]	Factors that should be considered include are special substances or equipment necessary for proper calibration	No	---	---	n/a

C.2.19 Does the medical device contain software

ID	Ref Question	Applys	Risk	Probability	Overall
[111]	Factors that should be considered include whether software is intended to be installed	No	---	---	n/a
[112]	Factors that should be considered include whether software is intended to be verified	No	---	---	n/a
[113]	Factors that should be considered include whether software is intended to be modified	No	---	---	n/a

ID	Ref Question	Applys	Risk	Probability	Overall
[114]	Factors that should be considered include whether software is intended to be exchanged	No	---	---	n/a

C.2.2 Is the medical device intended to be implanted

ID	Ref Question	Applys	Risk	Probability	Overall
[12]	Factors that should be considered include the location of implantation,	No	---	---	n/a
[13]	Factors that should be considered include the characteristics of the patient population	No	---	---	n/a
[14]	Factors that should be considered include the characteristics of the patient age	No	---	---	n/a
[15]	Factors that should be considered include the characteristics of the patient weight	No	---	---	n/a
[16]	Factors that should be considered include the characteristics of the patient physical activity	No	---	---	n/a
[17]	Factors that should be considered include the effect of ageing on implant performance	No	---	---	n/a
[18]	Factors that should be considered include the expected lifetime of the implant	No	---	---	n/a
[19]	Factors that should be considered include the reversibility of the implantation	No	---	---	n/a

C.2.20 Does the medical device have a restricted shelf-life

ID	Ref Question	Applys	Risk	Probability	Overall
[115]	Factors that should be considered include labelling	No	---	---	n/a
[116]	Factors that should be considered include indicators	No	---	---	n/a
[117]	Factors that should be considered include disposal of such medical devices	No	---	---	n/a

C.2.21 Are there any delayed or long-term use effects

ID	Ref Question	Applys	Risk	Probability	Overall
[118]	Factors that should be considered include ergonomic effects	No	---	---	n/a
[119]	Factors that should be considered include cumulative effects	No	---	---	n/a

C.2.22 To what mechanical forces will the medical device be subjected

ID	Ref Question	Applys	Risk	Probability	Overall
[120]	Factors that should be considered include whether the forces to which the medical device will be subjected are under the control of the user	No	---	---	n/a

ID	Ref Question	Applys	Risk	Probability	Overall
[121]	Factors that should be considered include whether the forces to which the medical device will be subjected are controlled by interaction with other persons	No	---	---	n/a

C.2.23 What determines the lifetime of the medical device

ID	Ref Question	Applys	Risk	Probability	Overall
[122]	Factors that should be considered include ageing	No	---	---	n/a
[123]	Factors that should be considered include battery depletion.	No	---	---	n/a

C.2.24 Is the medical device intended for single use

ID	Ref Question	Applys	Risk	Probability	Overall
[124]	Factors that should be considered include does the medical device self-destruct after use	No	---	---	n/a
[125]	Factors that should be considered include Is it obvious that the device has been used	No	---	---	n/a

C.2.25 Is safe decommissioning or disposal of the medical device necessary

ID	Ref Question	Applys	Risk	Probability	Overall
[126]	Factors that should be considered include the waste products that are generated during the disposal of the medical device itself	No	---	---	n/a
[127]	Factors that should be considered include does it contain toxic material	No	---	---	n/a
[128]	Factors that should be considered include does it contain hazardous material	No	---	---	n/a
[129]	Factors that should be considered include is the material recyclable	No	---	---	n/a

C.2.26 Does installation or use of the medical device require special training or special skills

ID	Ref Question	Applys	Risk	Probability	Overall
[130]	Factors that should be considered include the novelty of the medical device	No	---	---	n/a
[131]	Factors that should be considered include the likely skill and training of the person installing the device.	No	---	---	n/a

C.2.27 How will information for safe use be provided

ID	Ref Question	Applys	Risk	Probability	Overall
[132]	Factors that should be considered include whether information will be provided directly to the end user by the manufacturer NOTES: User instructions	Yes	Minor	Improbable	No Action
[133]	Factors that should be considered include will it involve the participation of third parties such as installers	No	---	---	n/a
[134]	Factors that should be considered include will it involve the participation of third parties such as care providers	No	---	---	n/a
[135]	Factors that should be considered include will it involve the participation of third parties such as health care professionals	No	---	---	n/a
[136]	Factors that should be considered include will it involve the participation of third parties such as pharmacists	No	---	---	n/a
[137]	Factors that should be considered include will it involve whether this will have implications for training	No	---	---	n/a
[138]	commissioning and handing over to the end user and whether it is likely/possible that installation can be carried out by people without the necessary skills	No	---	---	n/a
[139]	based on the expected life of the device, whether re-training or re-certification of operators or service personnel would be required	No	---	---	n/a

C.2.28 Will new manufacturing processes need to be established or introduced

ID	Ref Question	Applys	Risk	Probability	Overall
[140]	Factors that should be considered include new technology	No	---	---	n/a
[141]	Factors that should be considered include new scale of production.	No	---	---	n/a

C.2.29 Is successful application of the medical device critically dependent on human factors

ID	Ref Question	Applys	Risk	Probability	Overall
[142]	such as the user interface	No	---	---	n/a

C.2.29.1 Can the user interface design features contribute to use error

ID	Ref Question	Applys	Risk	Probability	Overall
[143]	Factors that should be considered are user interface design features that can contribute to use error	No	---	---	n/a
[144]	Examples of interface design features include control and indicators,	No	---	---	n/a
[145]	Examples of interface design features include symbols used,	No	---	---	n/a

ID	Ref Question	Applys	Risk	Probability	Overall
[146]	Examples of interface design features include ergonomic features	No	---	---	n/a
[147]	Examples of interface design features include physical design and layout,	No	---	---	n/a
[148]	Examples of interface design features include hierarchy of operation	No	---	---	n/a
[149]	Examples of interface design features include menus for software driven devices	No	---	---	n/a
[150]	Examples of interface design features include visibility of warnings,	No	---	---	n/a
[151]	Examples of interface design features include audibility of alarms	No	---	---	n/a
[152]	Examples of interface design features include standardization of colour coding	No	---	---	n/a

C.2.29.2 Is the medical device used in an environment where distractions can cause use error

ID	Ref Question	Applys	Risk	Probability	Overall
[153]	Factors that should be considered include the consequence of use error	No	---	---	n/a
[154]	Factors that should be considered include whether the distractions are commonplace	No	---	---	n/a
[155]	Factors that should be considered include whether the user can be disturbed by an infrequent distraction	No	---	---	n/a

C.2.29.3 Does the medical device have connecting parts or accessories

ID	Ref Question	Applys	Risk	Probability	Overall
[156]	Factors that should be considered include the possibility of wrong connections	No	---	---	n/a
[157]	Factors that should be considered include similarity to other products connections,	No	---	---	n/a
[158]	Factors that should be considered include connection force,	No	---	---	n/a
[159]	Factors that should be considered include feedback on connection integrity	No	---	---	n/a
[160]	Factors that should be considered include over- and under-tightening.	No	---	---	n/a

C.2.29.4 Does the medical device have a control interface

ID	Ref Question	Applys	Risk	Probability	Overall
[161]	Factors that should be considered include spacing,	No	---	---	n/a
[162]	Factors that should be considered include , coding,	No	---	---	n/a
[163]	Factors that should be considered include grouping,	No	---	---	n/a
[164]	Factors that should be considered include mapping,	No	---	---	n/a
[165]	Factors that should be considered include modes of feedback	No	---	---	n/a

ID	Ref Question	Applys	Risk	Probability	Overall
[166]	Factors that should be considered include modes of blunders	No	---	---	n/a
[167]	Factors that should be considered include slips	No	---	---	n/a
[168]	Factors that should be considered include control differentiation	No	---	---	n/a
[169]	Factors that should be considered include visibility	No	---	---	n/a
[170]	Factors that should be considered include direction of activation	No	---	---	n/a
[171]	Factors that should be considered include direction of change	No	---	---	n/a
[172]	Factors that should be considered include whether the controls are continuous or discrete	No	---	---	n/a
[173]	Factors that should be considered include the reversibility of settings or actions	No	---	---	n/a

C.2.29.5 Does the medical device display information

ID	Ref Question	Applys	Risk	Probability	Overall
[174]	Factors that should be considered include visibility in various environments	No	---	---	n/a
[175]	Factors that should be considered include orientation	No	---	---	n/a
[176]	Factors that should be considered include the visual capabilities of the user	No	---	---	n/a
[177]	Factors that should be considered include populations and perspectives	No	---	---	n/a
[178]	Factors that should be considered include clarity of the presented information	No	---	---	n/a
[179]	Factors that should be considered include units	No	---	---	n/a
[180]	Factors that should be considered include colour coding	No	---	---	n/a
[181]	Factors that should be considered include accessibility of critical information	No	---	---	n/a

C.2.29.6 Is the medical device controlled by a menu

ID	Ref Question	Applys	Risk	Probability	Overall
[182]	Factors that should be considered include complexity and number of layers	No	---	---	n/a
[183]	Factors that should be considered include awareness of state	No	---	---	n/a
[184]	Factors that should be considered include location of settings	No	---	---	n/a
[185]	Factors that should be considered include navigation method	No	---	---	n/a
[186]	Factors that should be considered include number of steps per action	No	---	---	n/a
[187]	Factors that should be considered include sequence clarity and memorization problems	No	---	---	n/a

ID	Ref Question	Applys	Risk	Probability	Overall
[188]	Factors that should be considered include importance of control function relative to its accessibility and the impact of deviating from specified operating procedures.	No	---	---	n/a

C.2.29.7 Will the medical device be used by persons with special needs

ID	Ref Question	Applys	Risk	Probability	Overall
[189]	Factors that should be considered include the user, their mental and physical abilities, skill and training, ergonomic aspects, the use environment, installation requirements, and the patient`s capability to control or influence the use of the medical device. Special attention should be paid to users with special needs, such as handicapped persons, the elderly and children. Their special needs might include assistance by another person to enable the use of a medical device. Is the medical device intended to be used by individuals with various skill levels and cultural backgrounds	No	---	---	n/a

C.2.29.8 Can the user interface be used to initiate user actions

ID	Ref Question	Applys	Risk	Probability	Overall
[190]	Factors that should be considered include the possibility of initiatinig a deliberate action for the user to enter a controlled operation mode, which enlarges the risks for the patient and which creates awareness for the user for this condition.	No	---	---	n/a

C.2.3 Is the medical device intended to be in contact with the patient or other persons

ID	Ref Question	Applys	Risk	Probability	Overall
[20]	Factors that should be considered include the nature of the intended contact	No	---	---	n/a
[21]	Factors that should be considered include the nature of the intended contact surface contact	No	---	---	n/a
[22]	Factors that should be considered include the nature of the intended contact invasive contact	No	---	---	n/a
[23]	Factors that should be considered include the nature of the intended the period of contact	No	---	---	n/a
[24]	Factors that should be considered include the nature of the intended the frequency of contact	No	---	---	n/a

C.2.30 Does the medical device use an alarm system

ID	Ref Question	Applys	Risk	Probability	Overall
[191]	Factors that should be considered are the risk of false alarms	No	---	---	n/a
[192]	Factors that should be considered are the risk of missing alarms	No	---	---	n/a

ID	Ref Question	Applys	Risk	Probability	Overall
[193]	Factors that should be considered are the risk of disconnected alarm systems	No	---	---	n/a
[194]	Factors that should be considered are the risk unreliable remote alarm systems	No	---	---	n/a
[195]	Factors that should be considered are the medical staffs possibility of understanding how the alarm system works	No	---	---	n/a

C.2.31 In what ways might the medical device be deliberately misused

ID	Ref Question	Applys	Risk	Probability	Overall
[196]	Factors that should be considered are incorrect use of connectors	No	---	---	n/a
[197]	Factors that should be considered are disabling safety features or alarms	No	---	---	n/a
[198]	Factors that should be considered are neglect of manufacturer`s recommended maintenance	No	---	---	n/a

C.2.32 Does the medical device hold data critical to patient care

ID	Ref Question	Applys	Risk	Probability	Overall
[199]	Factors that should be considered include the consequence of the data being modified	No	---	---	n/a
[200]	Factors that should be considered include the consequence of the data being corrupted.	No	---	---	n/a

C.2.33 Is the medical device intended to be mobile or portable

ID	Ref Question	Applys	Risk	Probability	Overall
[201]	Factors that should be considered are the necessary grips,	No	---	---	n/a
[202]	Factors that should be considered are the necessary handles,	No	---	---	n/a
[203]	Factors that should be considered are the necessary wheels,	No	---	---	n/a
[204]	Factors that should be considered are the necessary, brakes,	No	---	---	n/a
[205]	Factors that should be considered are, mechanical stability	No	---	---	n/a
[206]	Factors that should be considered are,durability	No	---	---	n/a

C.2.34 Does the use of the medical device depend on essential performance

ID	Ref Question	Applys	Risk	Probability	Overall
[207]	Factors that should be considered are the characteristics of the output of life-supporting devices	No	---	---	n/a
[208]	Factors that should be considered are the operation of an alarm	No	---	---	n/a

C.2.4 What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device

ID	Ref Question	Applys	Risk	Probability	Overall
[25]	Factors that should be considered include compatibility with relevant substances	No	---	---	n/a
[26]	Factors that should be considered include compatibility with tissues	No	---	---	n/a
[27]	Factors that should be considered include compatibility with body fluids	No	---	---	n/a
[28]	whether characteristics relevant to safety are known	No	---	---	n/a
[29]	is the device manufactured utilizing materials of animal origin	No	---	---	n/a

C.2.5 Is energy delivered to or extracted from the patient

ID	Ref Question	Applys	Risk	Probability	Overall
[30]	Factors that should be considered include the type of energy transferred	No	---	---	n/a
[31]	Factors that should be considered include the type of energy its control	No	---	---	n/a
[32]	Factors that should be considered include the type of energy its quality	No	---	---	n/a
[33]	Factors that should be considered include the type of energy its intensity	No	---	---	n/a
[34]	Factors that should be considered include the type of energy its duration	No	---	---	n/a
[35]	Factors that should be considered include whether energy levels are higher than those currently used for similar devices	No	---	---	n/a

C.2.6 Are substances delivered to or extracted from the patient

ID	Ref Question	Applys	Risk	Probability	Overall
[36]	Factors that should be considered include whether the substance is delivered NOTES: Oxygen will support combustion	Yes	Negligible	Improbable	No Action
[37]	Factors that should be considered include whether the substance is extracted	No	---	---	n/a
[38]	Factors that should be considered include whether it is a single substance	No	---	---	n/a
[39]	Factors that should be considered include whether it is a range of substances	No	---	---	n/a
[40]	Factors that should be considered include maximum transfer rates and control thereof	No	---	---	n/a
[41]	Factors that should be considered include minimum transfer rates and control thereof	No	---	---	n/a

C.2.7 Are biological materials processed by the medical device for subsequent

ID	Ref Question	Applys	Risk	Probability	Overall
[43]	re-use,	No	---	---	n/a
[44]	transfusion	No	---	---	n/a
[45]	transplantation	No	---	---	n/a

C.2.8 Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable

ID	Ref Question	Applys	Risk	Probability	Overall
[46]	Factors that should be considered include whether the medical device is intended for single use	No	---	---	n/a
[47]	Factors that should be considered include whether the medical device is intended for re-use packaging	No	---	---	n/a
[48]	Factors that should be considered include shelf-life issues	No	---	---	n/a
[49]	Factors that should be considered include limitation on the number of re-use cycles	No	---	---	n/a
[50]	Factors that should be considered include method of product sterilization	No	---	---	n/a
[51]	Factors that should be considered include the impact of other sterilization methods not intended by the manufacturer	No	---	---	n/a

C.2.9 Is the medical device intended to be routinely cleaned and disinfected by the user

ID	Ref Question	Applys	Risk	Probability	Overall
[52]	Factors that should be considered include the types of cleaning or disinfecting agents to be used	No	---	---	n/a
[53]	Factors that should be considered include any limitations on the number of cleaning cycles.	No	---	---	n/a
[54]	Factors that should be considered include The design of the Medical device can influence the effectiveness of routine cleaning and disinfection	No	---	---	n/a
[55]	Factors that should be considered include the effect of cleaning and disinfecting agents on the safety or performance of the device.	No	---	---	n/a

D.2 Energy hazards and contributory factors

ID	Ref Question	Applys	Risk	Probability	Overall
[222]	Mechanical force	No	---	---	n/a
[223]	Gravity Falling	No	---	---	n/a
[224]	Suspended masses	No	---	---	n/a
[225]	Stored energy	No	---	---	n/a
[226]	Torsion,Shear & Tensile	No	---	---	n/a
[227]	High Pressure Fluid injection	No	---	---	n/a
[230]	Moving parts	No	---	---	n/a
[231]	Moving & positioning patient	No	---	---	n/a

ID	Ref Question	Applys	Risk	Probability	Overall
[232]	Unintended motion	No	---	---	n/a
[233]	Patient support failure	No	---	---	n/a
[234]	Pressure vessel rupture	No	---	---	n/a
[235]	Acoustic pressure	No	---	---	n/a
[236]	Ultrasonic energy	No	---	---	n/a
[237]	Infrasound energy	No	---	---	n/a

D.3 Toxic hazards and contributory factors

ID	Ref Question	Applys	Risk	Probability	Overall
[241]	Bio-contamination NOTES: Single use product	Yes	Negligible	Improbable	No Action
[242]	Bacteria NOTES: Only if re used with a different patient	Yes	Negligible	Improbable	No Action
[243]	Viruses	No	---	---	n/a
[244]	Other agents prions	No	---	---	n/a
[245]	Bio-incompatibility	No	---	---	n/a
[246]	Incorrect formulation chemical composition	No	---	---	n/a
[247]	Toxicity	No	---	---	n/a
[248]	Allergenicity/ irritancy	No	---	---	n/a
[249]	Mutagenicity	No	---	---	n/a
[250]	Oncogenicity	No	---	---	n/a
[251]	Carcinogenicity	No	---	---	n/a
[252]	Re and/or cross infection NOTES: Only if used on different patients	Yes	Negligible	Improbable	No Action
[253]	Pyrogenicity	No	---	---	n/a

D.3.12 hygienic standards

ID	Ref Question	Applys	Risk	Probability	Overall
[254]	Degradation	No	---	---	n/a
[255]	Chemical	No	---	---	n/a
[256]	Acids or Alkalis	No	---	---	n/a
[257]	Contaminates	No	---	---	n/a
[258]	Processing aids	No	---	---	n/a
[260]	Testing aids	No	---	---	n/a
[261]	Medical gases	No	---	---	n/a
[262]	Anaesthetic products	No	---	---	n/a

D.4 Electromagnetic fields

ID	Ref Question	Applys	Risk	Probability	Overall
[268]	Operation outside prescribed environmental conditions	No	---	---	n/a
[270]	Accidental mechanical damage	No	---	---	n/a

ID	Ref Question	Applys	Risk	Probability	Overall
[271]	Contamination due to waste products and/or device disposal	No	---	---	n/a

D.5

ID	Ref Question	Applys	Risk	Probability	Overall
[274]	Volume	No	---	---	n/a
[275]	Supply of medical gases	No	---	---	n/a
[276]	Pressure	No	---	---	n/a
[277]	Supply of anaesthetic agents	No	---	---	n/a

D.6 Hazards related to the use of the medical device and contributory factors

ID	Ref Question	Applys	Risk	Probability	Overall
[279]	Inadequate operating instructions	No	---	---	n/a
[280]	Inadequate description of performance	No	---	---	n/a
[281]	Inadequate specification of intended use	No	---	---	n/a
[282]	Inadequate disclosure of limitations	No	---	---	n/a
[283]	Inadequate specification of accessories	No	---	---	n/a
[284]	Inadequate specification of pre-use checks	No	---	---	n/a
[285]	Over-complicated operating instructions	No	---	---	n/a
[286]	Inadequate specification of service and maintenance	No	---	---	n/a
[287]	Use by unskilled / untrained personnel	No	---	---	n/a
[288]	Reasonable foreseeable misuse	No	---	---	n/a
[289]	Insufficient warning of side effects	No	---	---	n/a
[290]	Incorrect measurement and other metrological aspects	No	---	---	n/a
[291]	Inadequate warnings of hazards likely with re-use of single use devices	No	---	---	n/a
[292]	Misrepresentation of results	No	---	---	n/a
[293]	Incompatibility with consumables / accessories / other devices	No	---	---	n/a
[294]	Sharp edges or points	No	---	---	n/a

D.7 Mistakes judgement errors

ID	Ref Question	Applys	Risk	Probability	Overall
[295]	Mistakes & judgement errors	No	---	---	n/a
[296]	Incorrect or inappropriate output or functionality	No	---	---	n/a
[297]	Erroneous data transfer	No	---	---	n/a
[298]	Loss or deterioration in function	No	---	---	n/a
[301]	Rule based failure	No	---	---	n/a
[302]	Knowledge based failure	No	---	---	n/a
[303]	Routine violation	No	---	---	n/a
[304]	Violation or abbreviation of instructions, procedures etc	No	---	---	n/a

ID	Ref Question	Applys	Risk	Probability	Overall
[308]	Misrepresentation of results	No	---	---	n/a
[311]	Controversial modes or mappings as compared to existing equipment	No	---	---	n/a

D.8

ID	Ref Question	Applys	Risk	Probability	Overall
[317]	Loss of mechanical integrity	No	---	---	n/a
[318]	Inadequate packaging contamination and / or deterioration of the device	No	---	---	n/a
[320]	Deterioration in function gradual occlusion of fluid / gas path or change in resistance to flow, electrical conductivity as a result of repeated use	No	---	---	n/a

D.9 Fire Risk

ID	Ref Question	Applys	Risk	Probability	Overall
[334]	In terms of the device itself	No	---	---	n/a
[335]	In term of materials used to clean	No	---	---	n/a

D.9 Fire Risk

ID	Ref Question	Applys	Risk	Probability	Overall
[336]	In terms of Materials passing through the device	No	---	---	n/a

D.10 Explosion Risk

ID	Ref Question	Applys	Risk	Probability	Overall
[337]	In terms of the device itself	No	---	---	n/a
[338]	In term of materials used to clean	No	---	---	n/a
[339]	In terms of Materials passing through the device.	No	---	---	n/a

Use By Dates

ID	Ref Question	Applys	Risk	Probability	Overall
[340]	Does the device have and time limitation on the safe use of the device. Note the USE-BY time limit refers to the period before the first use of the device, It does not relate to the number or period of subsequent uses (Lifetime) of the device	No	---	---	n/a

Reference Question 4
C.2.1 What is the intended use and how is the medical device to be used what is the medical devices role relative to treatment
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Action : Risk Benefits
Assessed By John Lamb
Assessed On 07/05/14
Further Information Issue : 0
Risk Completed

Reference Question 36
C.2.6 Are substances delivered to or extracted from the patient
Factors that should be considered include whether the substance is delivered
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Action : No Action
Assessed By John Lamb
Assessed On 05/10/15
Notes :
Oxygen will support combustion
Further Information Issue : 0
Risk Completed

Reference Question 56
C.2.10 Is the medical device intended to modify the patient environment
Factors that should be considered include temperature
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By John Lamb
Assessed On 07/05/14
Further Information Issue : 0
Risk Completed

Reference Question 57
C.2.10 Is the medical device intended to modify the patient environment
Factors that should be considered include humidity
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By John Lamb
Assessed On 07/05/14
Further Information Issue : 0
Risk Completed

Reference Question 58
C.2.10 Is the medical device intended to modify the patient environment
Factors that should be considered include atmospheric gas composition
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By John Lamb
Assessed On 07/05/14
Notes :
CO2 build up
Further Information Issue : 0
Risk Completed

Reference Question 66
C.2.13 Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies
Factors that should be considered include identifying any other medical devices
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By John Lamb
Assessed On 07/05/14
Further Information Issue : 0
Risk Completed

Reference Question 132
C.2.27 How will information for safe use be provided
Factors that should be considered include whether information will be provided directly to the end user by the manufacturer
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By John Lamb
Assessed On 05/10/15
Notes :
User instructions
Further Information Issue : 0
Risk Completed

Reference Question 241
D.3 Toxic hazards and contributory factors
Bio-contamination
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Action : No Action
Assessed By John Lamb
Assessed On 05/10/15
Notes :
Single use product
Further Information Issue : 0
Risk Completed

Reference Question 242
D.3 Toxic hazards and contributory factors
Bacteria
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Action : No Action
Assessed By John Lamb
Assessed On 05/10/15
Notes :
Only if re used with a different patient
Further Information Issue : 0
Risk Completed

Reference Question 252
D.3 Toxic hazards and contributory factors
Re and/or cross infection
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Action : No Action
Assessed By John Lamb
Assessed On 05/10/15
Notes :
Only if used on different patients
Further Information Issue : 0
Risk Completed

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Risk Assessment Document Summary Applicable questions and Actions

Ref Question	Applys	Risk	Risk Probability	Overall Risk	Assessed By	Assessed On	Risk Completed
4	Yes	Minor	Occasinal	Risk Benefits	John Lamb	07/05/14	Yes
36	Yes	Negligible	Improbable	No Action	John Lamb	05/10/15	Yes
56	Yes	Minor	Remote	No Action	John Lamb	07/05/14	Yes
57	Yes	Minor	Improbable	No Action	John Lamb	07/05/14	Yes
58	Yes	Minor	Remote	No Action	John Lamb	07/05/14	Yes
66	Yes	Minor	Remote	No Action	John Lamb	07/05/14	Yes
132	Yes	Minor	Improbable	No Action	John Lamb	05/10/15	Yes
241	Yes	Negligible	Improbable	No Action	John Lamb	05/10/15	Yes
242	Yes	Negligible	Improbable	No Action	John Lamb	05/10/15	Yes
252	Yes	Negligible	Improbable	No Action	John Lamb	05/10/15	Yes